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7590 Amerhsam Health, Inc. 101 Carnegie Center Princeton, NJ 08540		01/09/2008	EXAMINER GILBERT, SAMUEL G	
			ART UNIT 3735	PAPER NUMBER
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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/731,828  
Filing Date: December 09, 2003  
Appellant(s): FAULKNER ET AL.

**MAILED**  
**JAN 09 2008**  
**GROUP 3700**

\_\_\_\_\_  
Craig M. Bohlken  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 10/17/2007 appealing from the Office action mailed 3/28/2007.

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**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5460592	Langton	10-1995
5,863,790	Bolea	1-1999
6,106,455	Kan	08-2000

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-5, 7-10, 12, 13, 15, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langton et al(5,460,592) in view of Bolea(5,863,790).

Langton teaches a method of making and sterilizing a seed train. The applicant's attention is invited to column 2 lines 60-64, showing the method of heating and subsequently cooling to make the seed train semi-rigid. Column 3 lines 10-13 that teaches the device can be stiffened and sterilized at the same time using an autoclave.

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Autoclaves are known to use steam and dry heat. Column 6 lines 1-3 teaches using dry heat having a temperature range of 150-185 C for 1 hour to stiffen the material. The examiner is taking element -13- as a closed container. Sleeve -28- is gas impermeable. I-125 is set forth in column 5, lines 14-21. It is inherent that the seeds are free of moisture. Regarding claim 12 – the heat is dry heat as noted above, the applicant's attention is invited to column 6, line 1. However, Langton et al does not teach a time of at least two hours for sterilization. It is old and well known in the medical art that when using dry heat for sterilization the typical time period is at least two hours as shown by Bolea column 1 lines 39-42. As set forth in column 3, lines 10-13, an autoclave is used when a one step manufacturing process is used. To stiffen the seed strand at least one hour in the temperature range is set forth. The sterilizing step for the one step manufacturing is not set forth. Bolea sets forth that the typical dry heat sterilization process is a temperature range of dry heat of about 180 degrees Celsius for a time period of at least two hours. It would have been obvious to one of ordinary skill in the medical arts at the time the invention was made to use a time period of at least two hours for dry heat sterilization for the one step manufacturing step of Langton et al as set forth in Bolea to ensure the device is properly and completely sterilized.

Claims 9 and 19 - the seeds may be I-125 and Pd-103, column 5 lines 5-21.

Claim 10 – It is the examiner's position that the seeds of Langton et al are inherently free of moisture but if they would include moisture at the beginning of the dry heat sterilization process the seed would be free of moisture at the end of the dry heat sterilization process.

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Claim 14 – the applicant's attention is invited to the embodiment of figure 23.

Claim 18 - it is the examiner's position that the elements are isotropic, unless specifically designed to provide a dose distribution, which is not isotropic, the radiation distribution of most seeds known in the medical arts are isotropic. The applicant has provided no evidence that the seeds of Langton et al are out of the ordinary and therefore are considered to be isotropic.

Claims 7 and 15 - the devices after sterilization are shipped the end user. The end user would need to know what specific radiation train is contained in the sterile package to decide which seed train to use. Labels are well known in the medical arts to provide end users with the information they need. The examiner is taking official notice that end user package labels are well known in the medical arts and would have been obvious to use with the container of Langton et al. to provide the end user with the required information.

Claim 8 - when using an autoclave it is known to sterilize more than one instrument at the same time. It would have been obvious to one of ordinary skill in the art at the time the invention was made to sterilize more than one device at a time as a duplication of elements which is within the skill of one of ordinary skill in the art.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kan 6,106,455 in view of the combination of Langton et al (5,460,592) and Bolea(5,863,790) as applied to claim 1 above. Kan teaches sterilizing loose seeds with steam. Langton and Bolea teach using dry heat in the range claimed for the time claimed by the

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applicant. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use dry heat sterilization with the device of Kan as a substitution of functionally equivalent elements as taught by Langton et al and Bolea.

#### **(10) Response to Argument**

On page 3, of the substitute appeal brief the applicant argues "the Examiner can not make the assumption that Langton sterilizes the seed at least one hour longer after stiffening it when Langton does not even disclose or teach this let alone suggest it.

In response the Examiner would like to point out that the Examiner has not assumed that Langton sterilizes the seed at least one hour longer after stiffening it. If the Examiner believed Langton taught sterilizing the seed with dry heat for one hour after stiffening the device with dry heat the Examiner would have rejected the applicant's claims under 35USC 102 instead of 35 USC 103.

On page 4, first paragraph the applicant sets forth that "Langton vaguely discloses the use of gas or gamma irradiation."

The Examiner believes that Langton clearly sets forth a three step process of making the invention including heating the strand to stiffen the strand, packaging the strand and then sterilizing the packaged strand with radiation or gas. This is set forth in column 2 line 56 through column 3 line 9.

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Langton further sets forth that the strand may be heated/sterilized using an autoclave thus producing a "one step" manufacturing process.

In the second paragraph of page 4, the applicant argues that the Examiner agrees with the Appellants that Langton does not set forth dry heat sterilization in a process where the strand is stiffened and sterilized. The examiner disagrees, It is the examiner's position that Langton in the "one step" manufacturing process uses an autoclave(dry heat) to stiffen and sterilize the strand and that only the time required to "stiffen" the strand is set forth. Langton has not positively set forth that the time period of one hour of dry heat will both stiffen and sterilize the strand.

Further, the applicant argues that it would not have been obvious to choose dry heat for sterilization purposes in place of gamma or gas sterilization as set forth by the examiner, on page 5 of the office action. The section referred to by the applicant is part of a hypothetical set forth by the examiner and not part of the rejection. The language used by the examiner was inappropriate and been slightly reworded below to clearly set forth a two step process using dry heat sterilization.

The multistep process set forth as follows as set forth by Lagnton, column 2 line 56 through column 3 line 9. The seed strand would first be heated for one hour to stiffen the seed strand, column 6, lines 1 and 2. The seed strand would then be cooled as set forth in column 2 lines 62-65. After the strand is cooled the strand would be packaged and then sterilized by gas or gamma irradiation. This method would require



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the strand to be handled and moved between the stiffening and packaging steps and then handled and moved again between the packaging and sterilizing steps.

Langton does not set forth dry heat sterilization in a procedure where the strand is stiffened and sterilized separately. However, because dry heat is used in the autoclave cycle a "one step" manufacturing step would require the use of dry heat (gas or radiation would not stiffen the strand) in the sterilizing step as well. If dry heat were used in the multi step process the procedure would be as follows, the strand would be stiffened by dry heat for one hour, cooled, handled and transported to be dry heat sterilized for at least two hours which is what is old and well known as the standard in the art as shown by Bolea then the strand would be cooled and packaged, for a total time in dry heat of at least 3 hours.

Langton does set forth that the process of stiffening and sterilizing may be completed together to produce a "one step" manufacturing process. In this method, the strand would be placed in dry heat for at least two hours as shown by the combination of Langton et al and Bolea, the strand would be stiffened after the first hour of the heating while sterilization would not be finished until the strand has been in the dry heat for at least two hours.

Combining the steps of stiffening and sterilizing requires a total heating time of at least two hours while the method using separate stiffening and sterilizing with dry heat requires a total heating time of at least three hours.

Therefore, the combination of the teachings of Langton et al and Bolea would have been obvious in order to save time and the references do not teach away from an at least two hour time period as argued by the applicant.

On page 5, the applicant sets forth that dry heat sterilization would imply an attendant risk of internal pressure and that any rupture of the sheath would cause serious escape of radioactivity.

In response it is the examiners position that the seeds set forth in Langton are the same as the seeds set forth in the claims and therefor any pressure/rupture concerns would be the same for the applicant. The applicant has presented no evidence that there is any danger of rupture of the sheath of Langton.

On page 6 penultimate paragraph, the applicant argues that Langton teaches away from "dry heat sterilization". The examiner disagrees because a one-step manufacturing process using the autoclave would require dry heat as set forth in column 6 line 1, for the complete one step process, as set forth in column 3 lines 10-12.

The examiner disagrees because the applicant has failed to show that Langton et al sterilizes and stiffens the seed strand in only one hour. The examiner has pointed out above the one hour time period set forth by Langton et al is only for stiffening the seed strand and one hour is not generally considered sufficient for dry heat sterilization as set forth by Bolea.

On the top of page 7, the Appellants argue that "the examiner states that it is believed that Bolea teaches dry heat sterilization time periods even though Bolea does not teach dry heat sterilization at least like the present invention". The examiner has repeated below the paragraph from page 7 which the applicant is referring to and would like to point out that the examiner actually stated "The examiner has reviewed Bolea in its entirety and believes that the dry heat sterilization time period of at least two hours is clearly taught in Bolea."

"In response it is the examiner's position that the applicant is correct that Bolea does not teach dry heat sterilization of radioactive seeds. Bolea does however teach that the generally accepted time period for dry heat sterilization is two hours. The examiner has not used Bolea to show dry heat sterilization of radioactive seeds only the generally accepted time period for such sterilization. The examiner has reviewed Bolea in its entirety and believes that the dry heat sterilization time period of at least two hours is clearly taught in Bolea and nothing in Bolea teaches away from using such a time period in dry heat sterilization of radioactive seeds."

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The Examiner is clearly not adding personal views to the teaching of Bolea. The Examiner has previously pointed out and will again, column 2 lines 39-42 of Bolea where it is clearly set forth that "dry heat sterilization typically involves exposing the devices being sterilized to temperatures in a range of approximately 180 °C., or higher, for at least two hours".

In the second paragraph on page 7 the Appellant states "it is pure speculation as to how long Langton intended it would take to sterilize the sheath." The Examiner agrees and would like to point out that the length of time required for dry heat sterilization is set forth in Bolea. The Appellant also argues that neither Langton nor Bolea disclose, suggest or teach all the elements of the present invention. The examiner agrees that neither of the references alone teach the invention as claimed but The obvious combination of the references as set forth above by the examiner teaches the invention as claimed.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

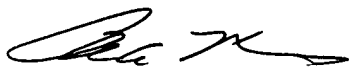
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

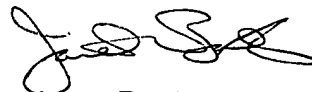
/Samuel G. Gilbert/

Primary Examiner, Art Unit 3735

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